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| EXAMINER |
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TREYGER, ILYA Y

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04/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/754,499 | Applicant(s) FREUND ET AL. | |
| | Examiner ILYA Y. TREYGER | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/20/2009 has been entered.
2. Claims 1, 19, and 24 are amended.
3. Claims 2 and 3 are canceled.
4. Rejection under 35 U.S.C. 112, second paragraph is withdrawn because of Applicant's amendment.
5. Claims 1 and 4-24 of the US Patent Application No. 10/754,499 filed 01/12/2004 are examined on the merits.

Response to Arguments

6. With respect to claims 1 and 19, Applicants argue that the V-shaped or T-shaped configuration of the welded seam is not a matter of an obvious design choice.

However, in light of newly brought reference Bodicky et al. (US 4,976,707) it is known to use the welded seam of the fluid collection bag of the V-shaped configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the welded seam of a collapsible bag of Osgar of the V-shaped configuration, as taught by Bodicky in order to utilize the collapsible bag of the conventionally known configuration.

7. Applicant's arguments, see Remarks, pages 10 and 11, filed 02/20/2009, with respect to the rejection(s) of claim(s) 20 under combination of Hughes and Osgar have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Schreiber (US 5,176,654).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 4, 5, and 13-19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Osgar et al. (US 5,102,010) in view of Bodicky et al. (US 4,976,707).

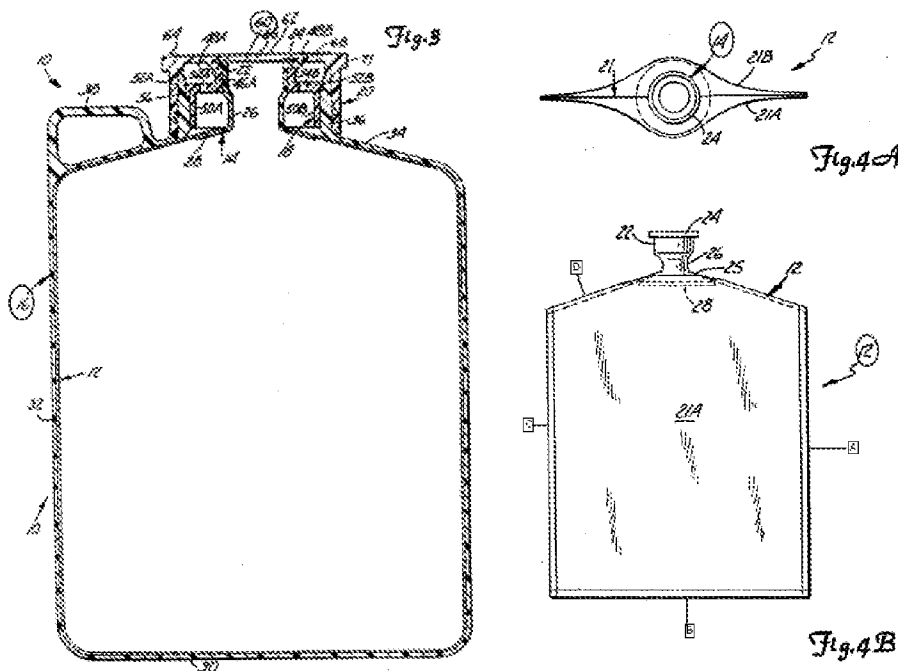
12. In Re claim 1, Osgar discloses a gas-tight and liquid-tight (Col. 4, ln. 21) container for a medical liquid including pharmaceuticals that includes

a collapsible (Col. 4, ln. 37-39) foil bag 12 (Col. 3, ln. 24) with a welded seam A,B,B,D;

a flange 14 with a passage through the flange and a sealing location within the flange.

The flange is sealed to the foil bag (Col. Abstract, ln. 5-6; Col. 3, ln. 36-38).

A pierceable membrane 60, which must be pierced (Col. 4, ln. 14-16) upon connection of the discharge member (See Figs. 3, 4A, and 4B).



Osgar does not expressly disclose the specific parameter of the pressure the foil bag is collapsible at.

The pressure collapsing the bag depends of the resistance of the walls of the bag (material the bag is produced from and thickness of the walls) and therefore is the matter of optimization.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)), therefore it would have been obvious to find the optimum value of the pressure in order to provide even discharge of the bag.

Osgar does not expressly disclose the bag having at least one welded seam of a substantially T-shaped or substantially V-shaped configuration.

Bodicky teaches a fluid collection bag (Abstract, line 1) having a welded seam of a V-shaped configuration (Col. 4, line 58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the welded seam of a collapsible bag of Osgar of the V-shaped configuration, as taught by Bodicky in order to utilize the collapsible bag of the conventionally known configuration.

13. In Re claim 4, Osgar discloses the container wherein the peirceable membrane is an integral portion of said flange and disposed at an end of or within said guide passage (See Col. 4, ln. 22-23; Fig. 3).

14. In Re claim 5, Osgar discloses the foil bag mad from a layered material (Col. 3, ln. 24-26).

15. In Re claim 13, Osgar discloses the container wherein the flange comprises a press fit 24 (See Fig. 4B).

16. In Re claim 14, Osgar in view of Bodicky disclose the claimed invention except for the press fit as a portion of the guide passage comprising a smooth inside wall of an inside diameter of said guide passage which only slightly differs from an outside diameter of the discharge connection member.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the press fit as claimed, because any press fit is a portion of the guide passage comprising either inside or outside wall slightly different in diameter from the diameter of the connection member.

17. In Re claim 15, Osgar in view of Bodicky disclose the claimed invention except the bulge portion as an element of press fit.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the press fit as claimed, because both bulge and wall inside or outside of the guide passage are variations of the bump.

Osgar does not expressly disclose the press fit comprising a plurality of bulges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use plurality of bulges (bumps) in a press fit to increase reliability of connection.

It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 MPEP 2144.04 (VI-B).

18. In Re claim 16, Osgar in view of Bodicky disclose the claimed invention discussed above but does not expressly disclose the specific location of the bulges on an inside wall of the guide passage.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to locate bulges on an inside wall of the guide passage because there are only two options for press fit elements location – on the inside or outside wall of the guide passage in dependence of the connection member configuration.

19. In Re claim 17, Osgar in view of Bodicky do not expressly disclose the plurality of bulges forming a plurality of ring portions of the press fit.

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to form plurality of rings from plurality of bulges to increase the reliability of the connection since said rings are another variation of bumps.

20. In Re claim 18, Osgar in view of Bodicky do not expressly disclose the bulges (bumps) of the helical configuration.

Since the criticality of making the bulge portions in the form claimed by Applicant is not supported by any showing of criticality of such placement in the instant specification, nor did Applicant stated that such form serves any specific purpose or performs any specific function other than the function disclosed in Osgar, it would have been obvious to those skilled in the art at the time the invention was made to make a bulge portions of a helical configuration because such modification would improve wear resistance of the press fit.

21. In Re claim 19, Osgar discloses a gas-tight and liquid-tight (Col. 4, ln. 21) container for a medical liquid including pharmaceuticals that includes

a collapsible (Col. 4, ln. 37-39) foil bag 12 (Col. 3, ln. 24) with a welded seam A,B,B,D;

a flange 14 with a passage through the flange and a sealing location within the flange.

The flange is sealed to the foil bag (Col. Abstract, ln. 5-6; Col. 3, ln. 36-38).

a pierceable membrane 60, which must be pierced (Col. 4, ln. 14-16) upon connection of the discharge member;

a first welded seam D for closing a first end of said foil bag, wherein said first welded seam extends substantially transversely with respect to the longitudinal direction of said foil bag;

a second welded seam A for sealing a first edge of said foil bag, wherein said second welded seam extends at least partially in the longitudinal direction of said foil bag; and

a third welded seam C for sealing a second edge of said foil bag, wherein said third welded seam extends at least partially in the longitudinal direction of said foil bag (See Figs. 3, 4A, and 4B).

Osgar does not expressly disclose the specific parameter of the pressure the foil bag is collapsible at.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

Osgar does not expressly disclose the bag having at least one welded seam of a substantially T-shaped or substantially V-shaped configuration.

Bodicky teaches a fluid collection bag (Abstract, line 1) having a welded seam of a V-shaped configuration (Col. 4, line 58).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

22. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osgar et al. (US 5,102,010) in view of Bodicky et al. (US 4,976,707) and further in view of Carlisle (US 3,878,977).

23. In Re claim 6, Osgar in view of Bodicky disclose the claimed invention discussed above, but do not expressly disclose a container wherein a first layer of said composite material includes a metal selected from the group consisting of aluminum, gold, and copper.

Carlisle teaches that it is known to use a container wherein the layer of the composite material includes an aluminum foil (Col. 9, ln. 21).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the foil of Carlisle into the invention of Osgar/Bodicky to improve thermal insulation of the medicament. Both inventions are drawn to fluid containment are analogous in the art and therefore a combination is proper.

24. In Re claim 7, Osgar discloses the container comprises an inner foil of a plastic material and an outer foil of a metal material (See Col. 3, ln. 24-26).

25. In Re claim 8, Osgar discloses the container comprises two foils of different plastic materials (See Col. 3, ln. 24-26).

26. In Re claim 9, Carlisle inherently discloses that it is known to make a flexible container of two layers wherein the melting temperature of second plastic material is higher than the melting temperature of the inner foil, since different plastics have different melting temperature (See Col. 9, ln. 23-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the flexible container of Osgar/ Bodicky from two different plastics, as taught by Carlisle, because such modification would simplify the production process.

27. In Re claim 10, Carlisle teaches that it is known to use a flexible container wherein the diffusion-tight central layer is made from a plastic material (See Col. 9, ln. 16-38).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

28. In Re claim 11, Carlisle teaches that it is known to make the outer foil of polyethylene terephthalate (See Col. 9, ln. 23).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

29. In Re claim 12, Carlisle teaches that it is known to make the inner foil of the flexible container of a polyethylene copolymer of ethylene-acrylic acid (See Col. 9, ln. 38).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

30. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010).

31. In Re claim 20, Schreiber discloses an atomizer (Col. 5, lines 41-45) with a discharge connection for dispensing medicament disposed in the attached vial 12 (Fig. 1) in predetermined doses (Col. 2, ln. 62-63), wherein the atomizer is interpreted as being gas-free, since no propellant gas has been used (Col. 4, lines 46-68; Col. 5, lines 1-12).

Hughe does not expressly disclose a collapsible container as claimed.

Osgar teaches that it is known to use a gas-tight and liquid-tight (Col. 4, ln. 21) container for a medical liquid including pharmaceuticals that includes

a collapsible (Col. 4, ln. 37-39) foil bag 12 (Col. 3, ln. 24) with a welded seam A,B,B,D;

a flange 14 with a passage through the flange and a sealing location within the flange.

The flange is sealed to the foil bag (Col. Abstract, ln. 5-6; Col. 3, ln. 36-38).

A pierceable membrane 60, which must be pierced (Col. 4, ln. 14-16) upon connection of the discharge member (See Figs. 3, 4A, and 4B).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vial of Schreiber with the collapsible container, as taught by Osgar, because such modification would decrease the cost of the system.

32. In Re claims 21 and 22, Schreiber/ Osgar disclose the claimed invention discussed above, but do not expressly disclose the specific dosage the medicament is taken in.

The particular dosage of medicament depends of the particular disease, condition of the patient, and patient's age, and therefore is the matter of optimization.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)).

33. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010) and further in view of Kief (US 6,303,152).

Schreiber in view of Osgar disclose the claimed invention discussed above, but do not expressly disclose the medicament in a solution of ethanol, water, or a mixture thereof.

Kief teaches that it is known to use water (Col. 6, ln. 43-44) as a solvent for inhalable solutions (Col. 3, ln. 36-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Schreiber/ Osgar with the medicament in a solution of water, as taught by Kief, because such modification would simplify the sterilization process of the medicament.

34. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010), as applied to claim 20 above, and further in view of Andersson et al. (US 5,934,273).

Schreiber in view of Osgar disclose the claimed invention discussed above, but do not expressly disclose the medicament including at least one active substance selected from the group consisting of one or more of the following: BEROTEC (fenoterol-hydrobromide; 1-(3,5-dihydroxyphenyl)-2-[[1-(4-hydroxybenzyl)-ethyl]-amino]-ethanol-hydrobromide), ALTROVENT (ipratropium bromide), BERODUAL (combination of fenoterol-hydrobromide and ipratropium-bromide), SALBUTAMOL or LBUTEROL, COMBIVENT, OXIVENT (oxitropium bromide), BA 679 (tiotropium bromide), BEA 2108 (di-(2-thienyl)-glycol acid tropenol ester), FLUNISOLID, BUDESONID, BECLOMETHASON.

Andersson teaches that it is known to use SALBUTAMOL and BUDESONID for inhalation purposes (Col. 4, ln. 11, 18)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Schreiber/ Osgar with the SALBUTAMOL and BUDESONID, as taught by Andersson, because such modification would allow the system to be used in cases when claimed medicaments are required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
Primary Examiner, Art Unit 3761